UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	:	**Hon. Robert B. Kugler**
	:	**Civil No. 1:19-md-2875-RBK-JS**
This Document Relates to:	:	
All Actions	:	

AUROBINDO PHARMA LTD.'S BRIEF IN SUPPORT OF MOTION FOR PROTECTIVE ORDER REGARDING THE DEPOSITION OF DR. A RAM MOHAN RAO AND PRODUCTION OF HIS CUSTODIAL FILE

Defendant Aurobindo Pharma Ltd. (hereinafter referred to as "Aurobindo") by and through its undersigned counsel, hereby submits this Brief in Support of its Motion for Protective Order to preclude the deposition of its Chief Quality Officer Dr. A Ram Mohan Rao and the production of his custodial file and in support thereof states as follows:

I. FACTUAL BACKGROUND

The Aurobindo Defendants have produced over 340,000 pages of documents and are in the process of producing custodial files for 15 individuals. Aurobindo Pharma Ltd. has produced over 200,000 pages of documents to the Plaintiffs, including over 30,000 documents responsive to the Court's Order on core discovery [see Dkt. 88] and 4 custodial files. It is also in the process of reviewing 4 more

custodial files and collecting an additional 10 to be produced. In addition, last year, Defendants Aurobindo Pharma USA, Inc. and Aurolife Pharma, LLC (collectively "the U.S. entities") produced 15 custodial files to Plaintiffs. Of those 15 custodians, Plaintiffs have requested to depose seven. Those depositions, along with the deposition of one additional custodian, are scheduled to take place over the next several months.

On February 4, 2021, the Court ordered the parties to submit their agreed-upon schedule of depositions no later than February 17, 2021 because all disputes would be addressed "no later than February 22, 2021." Accordingly, counsel for the Plaintiffs and the Aurobindo parties met and conferred and reached an agreement on a deposition schedule. [See Dkt. 942, p. 4.]. Now, in their Position Statement dated March 9, 2021, and during the conference on March 10, 2021, Plaintiffs ask the Court to circumvent Federal Rule of Civil Procedure 7(b) and order Aurobindo Pharma Ltd. to produce the custodial file of its Chief Quality Officer, Dr. A Ram Mohan Rao (hereinafter "Dr. Rao") and produce him for a deposition. [See Dkt. 1011, pp. 22-23]. In Defendants' Position Statement, and during the conference, defense counsel argued that Plaintiffs failed to establish good cause for why their late request should be granted, and asked the Court to enter an order precluding Plaintiffs request for any additional depositions and/or custodial files. Plaintiffs have failed to file a motion to this effect, in direct disregard of F.R.C.P. 7(b).

Before Aurobindo Pharma Ltd. was served in this litigation, Plaintiffs' asked the U.S. entities if they would agree to include Dr. Rao as a custodian. The U.S. entities refused and explained to Plaintiffs that Dr. Rao is employed with Aurobindo Pharma Ltd. Plaintiffs did not raise Dr. Rao since then, until now. They did not respond to Aurobindo's list of proposed custodians in August 2020, nor did they raise Dr. Rao when counsel met and conferred on several dates in January and February of 2021. They also chose not to include Dr. Rao among the 19 other custodians they asked the Court to Order Aurobindo Pharma Ltd. to produce in their Position Statement filed on March 9th. [See Dkt. 967 at pp. 7-10].

As Chief Quality Officer, Dr. Rao is a high-level official at the "apex" of Aurobindo. Forcing him to appear for a deposition and to produce his entire custodial file is unnecessary and unduly burdensome. Moreover, this Court previously denied Plaintiffs' request for another Manufacturer Defendant to add an individual to its list of custodians and produce an additional custodial file. Plaintiffs asked the Court to require Mylan to produce the custodial file of a certain individual whom Mylan designated as a Rule 30(b)(6) witness. The Court denied the request without prejudice to Plaintiffs' right to move for the production in the future for good cause shown. [See Dkt. 727 at paragraph no. 1]. The Court should deny Plaintiffs' request to the Aurobindo parties as well. Indeed, Plaintiffs' request directed to the Aurobindo parties is even more objectionable and burdensome given that the

Aurobindo parties have not designated Dr. Rao as a Rule 30(b)(6) witness. Therefore, Aurobindo respectfully requests that this Court deny Plaintiffs request for Dr. Rao's deposition and custodial file.

II. ARGUMENT

Federal Rule of Civil Procedure 26 requires courts to limit discovery otherwise allowed by the rules if it determines that "the discovery sought is unreasonably cumulative or duplicative, or can be obtained from some other source that is more convenient, less burdensome, or less expensive." F.R.C.P. 26(b)(2)(C)(i). In light of this rule, and because courts recognize that the depositions of corporations' executives and other high-ranking officials impose a heavy burden on these individuals and the companies they represent, they have developed a framework referred to as the "apex doctrine" to assess whether to permit the depositions of these high-level employees. *See United States ex rel. Donald R. Galmines, et al. v. Novartis Pharmaceuticals Corp.* No. 06-3213, 2015 WL 4973626, at *2. In applying the apex doctrine, courts should consider (i) whether the high-level official has personal or superior unique knowledge of the facts alleged and (ii) whether the information could be obtained from lower level employees or through less burdensome means. *See id.* (citing *In re Tylenol (Acetaminophen) Mktg., Sales Practices & Products Liab. Litig.*, No. 2:13-MD-02436, 2014 WL 3035791, at *3 (E.D. Pa. July 1, 2014).

In *United States ex rel. Galmines, et al. v. Novartis Pharmaceuticals Corp.*, the U.S. District Court for the Eastern District of Pennsylvania granted a motion to quash the subpoena for the deposition of the former CEO of Novartis Alex Gorsky, holding that the plaintiff did not overcome the presumption of the apex doctrine that the burden or expense of the deposition would outweigh its benefit. *See Galmaines* at *5. In that case, Judge Pratter noted that the plaintiff Mr. Galmines had failed to articulate how any information sought from Mr. Gorsky was specifically tied to any material matter in the case and provided no reason why the information sought could not be obtained through other means. *See id.* at *4. Furthermore, Mr. Galmines did not ascertain Mr. Gorsky's personal involvement in the alleged actions from the 18 other individuals he had already deposed, including six corporate representatives of Novartis and 12 fact witnesses. *See id.* at *5.

Judge Pratter cites to another case, *In re Tylenol (Acetaminophen) Mktg., Sales Practices & Products Liab. Litig.*, with circumstances that are distinguishable from *Galmaines* and from our case, as an example of when the apex doctrine would not apply. Unlike in *Galmaines*, where the plaintiff provided only generic assertions of Mr. Gorsky's involvement and knowledge of the material issues, in *Tylenol*, Judge Stengel refused to enter a protective order because "documents, which have been produced by the defendants during discovery show very clearly that [the high-ranking executive] was actively involved in decision making regarding the

marketing and product development of Tylenol products . . . They also indicate that [he] has knowledge that is unique to him and which could not be obtained through the depositions of those other . . . employees not quite at the 'apex.'" *See id.*, quoting *In re Tylenol*, No. 2:13-MD-02436, 2014 WL 3035791 (E.D. Pa. July 1, 2014)

The case at bar is almost identical to *Galmines*, and Plaintiffs have failed to rebut the apex doctrine's presumption that the burden of the deposition of a high-level employee such as Dr. Rao outweighs any benefit. Plaintiffs' only basis for requesting Dr. Rao's deposition is that he signed Aurobindo's response letter to the FDA's 483 notice, is listed as point person relating to the recall, and participated in meetings with the FDA. (See Plaintiff's Position Statement dated March 9, 2021, at pages 22 – 23.) Despite having had possession of FDA inspection reports mentioning Dr. Rao's name since June 2020, Plaintiffs waited until now to request his custodial file and deposition. They delayed reviewing documents produced months ago that clearly mention Dr. Rao, and they chose not to raise him during multiple meet and confers with defense counsel regarding custodians for Aurobindo Pharma Ltd. Counsel proposed a list of custodians in August 2020. Plaintiffs failed to respond. They also failed to raise Dr. Rao during several meet-and-conferrals with defense counsel in January and February of 2021, and they certainly did not include him among the 19 custodians they asked the Court to compel Aurobindo to produce in their Position Statement filed on March 9th. Simply put, Plaintiffs have no good

cause for seeking Dr. Rao's custodial file or his deposition, particularly given their delay and their failure to meet-and-confer in good faith with defense counsel. Despite having over nine months to determine their strategy, they are still unable to present any specific evidence as to why Dr. Rao's deposition is needed. They have not indicated any superior knowledge unique to him that they cannot obtain from lower-level employees who have direct and personal knowledge of the material matters in dispute. Dr. Rao's testimony would be unnecessarily cumulative and duplicative.

Moreover, there are more convenient and less burdensome ways for Plaintiffs to obtain the information they seek. In 2020, Defendants produced 15 custodial files from Aurolife and Aurobindo USA, and Plaintiffs have requested the depositions of seven of those custodians plus one additional custodian who Defendants agreed to add to the list. Two of those depositions are scheduled to occur this month, four in April, and two in May. Four are depositions pursuant to Federal Rule of Civil Procedure 30(b)(6). In addition, Aurobindo Pharma Ltd. has produced over 200,000 pages of documents including over 30,000 responsive to the Court's Order on core discovery [see Dkt. 88] and 4 custodial files, and is in the process of collecting and reviewing 15 more custodial files. Plaintiffs cannot provide any legitimate reason why they will not be able to obtain the information they desire from these depositions that are already scheduled or from the files already produced or agreed to be

produced. They allege that they are concerned the custodians already provided are not the right people, however they have not yet attempted to ascertain what knowledge these individuals possess. Plaintiffs' request is premature, if not harassing.

If Plaintiffs' request is granted, it will delay the current litigation schedule. Aurobindo Pharma Ltd. will have to devote time and resources to collect and review an additional custodial file, which may hold up production of the 15 other files to be produced. Plaintiffs may request to re-schedule certain depositions until the documents are produced and/or seek to re-depose witnesses despite their own delay.

This Court has already recognized that some of the depositions Plaintiffs are requesting may turn out to be unnecessary after the agreed-upon depositions take place. In December 2020, after the ZHP parties identified seven China-based witnesses and six U.S.-based witnesses to testify as to Plaintiffs' Court-approved 30(b)(6) topics, Plaintiffs requested seven additional depositions. (See Dkt. No. 858 at pg. 2.) ZHP agreed to two of those seven. Plaintiffs' were granted leave to depose the additional individuals without prejudice to ZHP to file a motion for protective order. However, Judge Schneider also pointed out that after the fifteen agreed-upon depositions take place "Plaintiff may decide [the disputed witnesses' testimony] is not needed because it's duplicative . . ." 12/22/2020 Hrg. Tr., at 40:24-41:6. Aurobindo has already agreed to produce eight custodians for deposition, and

Plaintiffs must exhaust those opportunities to obtain the relevant evidence before they can even determine whether this additional deposition of Dr. Rao is warranted.

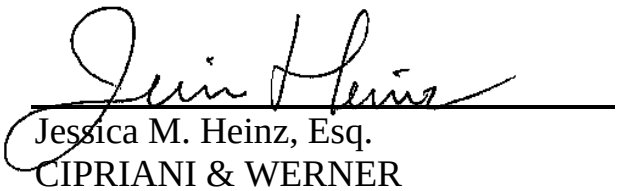
This is not the first time the Plaintiffs have tried to add custodians to the Manufacturer Defendants' court-approved lists. Indeed, in January of this year, the Court denied Plaintiffs' request for Mylan to add an individual to its list of custodians and produce an additional custodial file. The individual was someone whom Mylan designated as a Rule 30(b)(6) witness. The Court denied the request without prejudice to Plaintiffs' right to move for the production in the future for good cause shown. [See Dkt. 727 at paragraph no. 1]. Plaintiffs' request directed to the Aurobindo parties is even more objectionable and burdensome given that the Aurobindo parties have not designated Dr. Rao as a Rule 30(b)(6) witness. Therefore, and for all of the foregoing reasons, the Court should deny Plaintiffs' request with prejudice.

III. CONCLUSION

Allowing Plaintiffs to depose Aurobindo's Chief Quality Officer and obtain his custodial file when they are already in possession of numerous other custodial files and have requested the depositions of eight other individuals would create an undue burden on Aurobindo and Dr. Rao that clearly outweighs any potential benefit to Plaintiffs. Plaintiffs have not shown that Dr. Rao possesses any superior unique knowledge of the material issues in this case nor that they will be unable to obtain

the information they seek through other means. As a result, Aurobindo respectfully requests that this Court grant its Motion for Protective Order and preclude Plaintiffs from deposing Dr. Rao and from obtaining his custodial file.

Respectfully submitted,



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